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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,969	12/17/2001	John M. Irving	084/002	6623

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	7

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,969	IRVING ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *5, 6, 8 and 12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7 and 9-11* is/are rejected.

7)☒ Claim(s) *3 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I , with the additional election of the Y-box transactivator YB-1 (A) and the tissue specific promoter TERT (M) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that it would not pose a serious burden to search all groups I-IX and (A)-(R). This is not found persuasive because the groups listed in (A)-(R) are structurally different, because they comprise different sequences. In order to be considered a proper species and thereby be entitled to Markush restriction practice (see MPEP 8.03.02) the different inventions listed in (A)-(R) must share (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. Here the inventions (A)-(R) are sequences from different viruses and sequences from different tissues, therefore, they lack a substantial structural feature essential for the ultility and restriction among the inventions is proper.

Upon review of the Restriction/Election requirement of Paper 5, claims 1 and 13 should have been indicated as being linking claims.

Claim 1 link(s) inventions (A)-(E) and (F)-(R). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or

nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 13 link(s) inventions III-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 13. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

> To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed

product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See specifically page 13, line 7. Applicant is advised that this may not be the only embedded hyperlink in the specification.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 3 and 4, are attached to the instant Office Action.

Drawings

The drawings have been approved by the Draftsperson.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "or another gene required for replication or assembly of the virus" renders the claim indefinite because the phrase is enclosed in parenthesis, it is unclear whether the limitations inside the parenthesis are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Schiff (US 2002/0128221 A1).

The instant invention is drawn to a replication-conditional adenovirus which has at least one gene that replaces "a function of E1a gene". The specification describes a gene (or genetic element) as an element that can be replaced as long as it can be packed at a sufficient rate (see

page 8, line 7). Gene sequences (genetic elements) have been described to include promoters (see page 6, line 5). The specification indicates that something less than an entire coding region is contemplated by the term gene. Therefore, the replacement of functional promoter with the E1a promoter would satisfy the requirement of "at least one heterologous gene that replaces a function of the adenovirus E1a gene".

Schiff discloses the use of the hTERT promoter (paragraph 0062) for the control of the glycosyltransferase encoding region and the control of adenoviral genes required for replication (paragraph 0070, 0089 and 0090). Therefore, the instant invention is anticipated by Schiff.

Claims 1, 2, 7, 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Morin et al. (WO 00/46355, see IDS).

The instant invention is drawn to a replication-conditional adenovirus which has at least one gene that replaces "a function of E1a gene". The specification describes a gene (or genetic element) as an element that can be replaced as long as it can be packed at a sufficient rate (see page 8, line 7). Gene sequences (genetic elements) have been described to include promoters (see page 6, line 5). The specification indicates that something less than an entire coding region is contemplated by the term gene. Therefore, the replacement of functional promoter with the E1a promoter would satisfy the requirement of "at least one heterologous gene that replaces a function of the adenovirus E1a gene".

Morin et al. discloses the use of the hTERT promoter in an oncloytic virus, a replication conditional adenovirus where the genetic element essential for replication is the adenovirus E1a region (see claims). Therefore, the instant invention is anticipated by Morin et al.

Claims 1, 2, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Henderson et al. (U.S. Pat. No. 5,871,726).

The instant invention is drawn to a replication-conditional adenovirus which has at least one gene that replaces "a function of E1a gene". The specification describes a gene (or genetic element) as an element that can be replaced as long as it can be packed at a sufficient rate (see page 8, line 7). Gene sequences (genetic elements) have been described to include promoters (see page 6, line 5). The specification indicates that something less than an entire coding region is contemplated by the term gene. Therefore, the replacement of functional promoter with the E1a promoter would satisfy the requirement of "at least one heterologous gene that replaces a function of the adenovirus E1a gene".

Henderson et al. disclose the use of a cytotoxic adenovirus where the adenovirus gene essential for propagation is under the transcriptional control of the prostate specific response element the adenovirus additional comprises a transgene that is under the control of the same prostate specific response element (see claims 1-4). Therefore the instant invention is anticipated by Henderson et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 7, 9-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 7 and 11-14 of copending Application No. 09/994,427.

The instant invention is drawn to a replication-conditional adenovirus which has at least one gene that replaces "a function of E1a gene". The specification describes a gene (or genetic element) as an element that can be replaced as long as it can be packed at a sufficient rate (see page 8, line 7). Gene sequences (genetic elements) have been described to include promoters (see page 6, line 5). The specification indicates that something less than an entire coding region is contemplated by the term gene. Therefore, the replacement of a heterologous functional promoter with the E1a promoter would satisfy the requirement of "at least one heterologous gene that replaces a function of the adenovirus E1a gene".

Schiff discloses the use of the hTERT promoter (paragraph 0062) for the control of the glycosyltransferase encoding region and the control of adenoviral genes required for replication (paragraph 0070, 0089 and 0090). A polynucleotide is defined plasmids and vectors (paragraph 0036). Therefore, the instant invention over claims 1, 5, 6, 7 and 11-14 of copending Application No. 09/994,427

This is a provisional obviousness-type double patenting rejection.

Claim Objections

Claims 3 and 4 are objected to because of the following informalities: The claims are dependent on a rejected claim. Appropriate correction is required.

Conclusion

Claims 1,2, 7 and 9-11 are rejected

Claims 3 and 4 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 4/18/03